REMARKS

By the foregoing amendment, claims 1 and 3 have been amended and all the remaining claims have been canceled. Support for the amendment can be found in the original disclosure, for example, in the specification begins on page 5, line 13, to page 6, line 13. Accordingly, the foregoing amendment does not raise the issue of new matter.

Reconsideration of the previous rejection of the claims under 35 U.S.C. §103(a) as being unpatentable over Gast et al, WO 99266556, Hess et al and DeLuca et al are respectfully requested in view of the foregoing amendments and the attached declaration submitted under the provisions under 37 C.F.R. §1.132. The Examiner bases his position of obviousness on the presumption that one skilled in the art would have prepared additional beneficial compositions for the treatment of hypercalcemia/hypocalcemia by intravaginal administration because the reference teach vaginal devices. Because the prior art teaches the use of 1,25-dihydroxyvitamin D_3 and its' metabolic activity, and the reference also teach that vaginal devices can be used to administer drugs, having this knowledge at the time of the invention, one skilled in the art would have been motivated to use vitamin D per vaginal use.

Applicants respectfully disagree. As set forth in the attached declaration under 37 C.F.R. §1.132 it can be demonstrated that there is a dose-dependent absorption in the case where 1,25-dihydroxyvitamin D_3 (hereinafter sometime referred to as "$1,25(OH)_2D_3$" or "calcitriol") is transvaginally administered to a cow according to the present invention which effect is not obtained in the case of oral administration of the same vitamin D derivative.

Moreover, in the case where 1,25-dihydroxyvitamin D_3 is transvaginally administered to a cow according to the present invention bio-availability

(approximately 93%) of 1,25-dihydroxyvitamin D_3 is markedly high compared with that (approximately 62%) available by oral administration.

These assertions are supported by the attached showings in the Rule 132 declaration under heading "Dose Appendix" of the present invention as well as in relation to the comparative test and particular with regards to the "intravaginal administration calcitriol" as compared to "oral administration of calcitriol".

The bioavailability is supported by the showings contained in the Rule 132 Declaration.

In view of the foregoing, Applicants respectfully request reconsideration of the preceding rejections insofar as Applicants have presented evidence showing an unexpected superiority of the claimed invention as compared to previously known methods of administration of 1,25-dihydroxyvitamin D_3.

Regarding the previous comments on page 3 of the Office Action, Applicants respond as follows. The citation "U.S. 322462" on page 1, line 25, should read "USSN 322462, abandoned in favor of USSN 362,339 which matured into U.S. Patent No. 3,901,928." Accordingly, Applicants have amended the specification to refer to this correction. For the Examiner's information, a copy of the Hess et al, U.S. Patent No. 3,901,928, has already been submitted in an Information Disclosure Statement and acknowledged by the Examiner in the last Office Action.

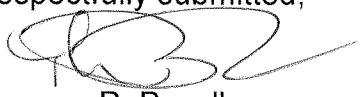
There are no copending applications which are "material to patentability" known to Applicants, their assignee or the undersigned.

In response to the Examiner's presumption that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absence any evidence to the contrary, Applicants affirm that presumption.

Having fully responded to the preceding Office Action, favorable reconsideration is respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8721.004.US0000.

Respectfully submitted,



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